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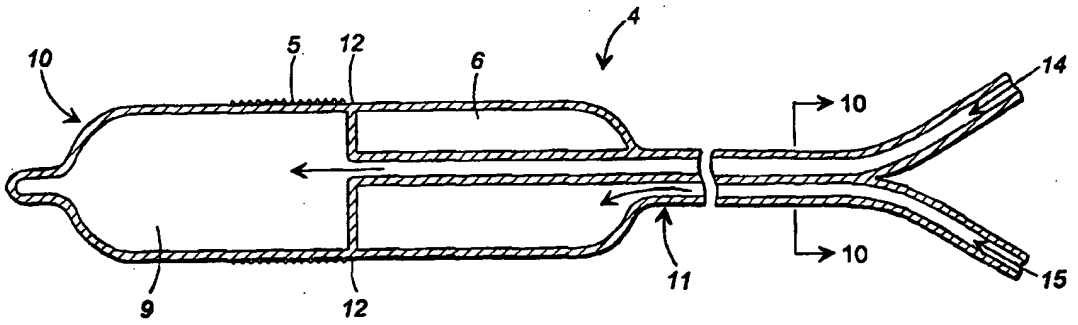

(57) Abstract

A new catheter (4) with two balloons (6, 9) precisely places a stent (5) at the ostium or junction (12) of a variety of bodily tissues, including the junction (12) of any artery, and an aorta to afford improved treatment of stenotic lesions (2).

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CATHETER AND METHOD OF OSTIAL STENT PLACEMENT

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

The present invention relates to a catheter, and more particularly, to a balloon catheter and method for the precise implantation of a stent at an ostial treatment site.

DESCRIPTION OF BACKGROUND AND RELATED ART

Stents are commonly placed or implanted within blood vessels to treat narrowing or other imperfections of the vessel walls. In particular, stents have been proven to be an effective treatment for stenosis of coronary arteries following angioplasty. Approximately 30 % of all angioplasty patients exhibit stenosis after angioplasty. Stent use has been shown to reduce the incidence both of acute closure, as well as chronic renarrowing of the coronary arteries post-angioplasty.

In clinical practice, a stent is typically delivered to the treatment site by a balloon catheter. At the treatment site, the stent is expanded by inflation of a balloon catheter to contact the vessel walls, by either the deployment catheter itself or a second expansion balloon catheter. Alternatively, a self-expanding stent can be employed. A variety of stents suitable for this purpose are known in the art. Once the stent is fixed in an appropriate position within the vessel, the balloon catheter is removed.

Conventional techniques, however, have proven unsatisfactory for ostial stent placement. An ostium is formed by the junction of a main vessel with a branched vessel. Precise stent placement at an ostial opening is difficult, and often results in misplacement of the stent. For coronary stents, for example, the stent is sometimes placed distal to the lesion, resulting in inadequate treatment of the stenosis. If the stent is placed too proximally at the ostial site, a portion of the stent will protrude into the aorta, providing a potential nidus for formation of thrombus and emboli.

SUMMARY OF THE INVENTION

Applicants have devised a new catheter to precisely position a stent at any ostia within the body. Precise placement of a stent in ostia forming junctions of branch vessels with main vessels, e.g., artery and aorta, is achieved with a novel catheter device having two or more balloons. Selective inflation of the balloons affords such precise placement by wedging the stent in the correct position.

Because stenosis of the ostium of the coronary artery has a higher incidence of acute closure and restenosis when compared to narrowings at other locations in the artery, the device of the present invention is particularly suitable for placement of intra-arterial stents. Other locations include intra-venous ostia, or ostia of other bodily structures, such as ureters, trachea, or bile ducts.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a cross-section of a main vessel and a branch vessel, with stenotic lesions at the ostium or junction.

Figure 2 shows the misplacement of a stent too distal from the junction of the main vessel and the branch vessel, thereby not repairing or treating the stenotic lesions.

Figure 3 shows an alternative misplacement of the stent, too proximal to the junction of the main vessel and the branch vessel, to overhang into the main vessel.

Figure 4 depicts appropriate placement of a stent at the junction of a main vessel and the branch vessel, an arrangement the device of the present invention is intended to achieve.

Figure 5 schematicaly illlustrates the catheter of the present invention, without full inflation, but with stent mounted thereon, and partially inserted into the ostium to be treated.

Figure 6 schematically illustrates the catheter of the present invention, with proximal inflatable balloon inflated to function as a stop wall device.

Figure 7 schematically illustrates the catheter of the invention, with stent mounted thereon, inserted into the ostium to be treated, with both the proximal and distal balloons inflated.

Figure 8 schematically illustrates the catheter of the invention, deflated and withdrawn after placement of the stent, according to the present invention.

Figure 9 schematically illustrates a cutaway view of one kind of catheter of the present invention, with stent mounted thereon, showing that the lumen accessing the distal inflatable balloon is bonded to or exists as an integral part of the tubular body of the catheter.

Figure 10 schematically illustrates a cross-sectional view of the catheter of Figure 9, showing two lumens.

Figure 11 schematically illustrates a cutaway view of another kind of catheter of the present invention, with stent mounted, showing that the lumen accessing the distal inflatable balloon is without attachment to or bonding to the inner surface of the tubular body of the catheter.

Figure 12 schematically illustrates a cross-section view of the catheter of Figure 11, showing two lumens.

Figure 13 schematically illustrates a cutaway view of another kind of catheter of the invention, with stent mounted, showing a third lumen for a guidewire to aid in placement of the catheter into the ostium to be treated and repaired.

Figure 14 schematically illustrates a cross-section view of the catheter of Figure 13, showing three lumens.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a device for implanting an ostial stent, comprising

a catheter, said catheter having a proximal end and a distal end relative to the surgeon or other medical personnel;

a distal inflatable balloon for setting a stent;

a first inflation lumen, extending through or outside of the catheter to permit inflation and deflation of the distal inflatable balloon;

a proximal inflatable balloon as a stop wall device, said proximal inflatable balloon forming a junction with said distal balloon; and

a second inflation lumen, extending through or outside of the catheter to permit inflation and deflation of the proximal inflatable balloon.

In one embodiment of the present invention, the device further comprises a stent, mountable on the distal inflatable balloon, said stent terminating at or distal to the junction of the proximal inflatable balloon and the distal inflatable balloon.

In another embodiment of the present invention, the device further comprises a central lumen extending through the catheter, the central lumen receiving a guidewire therethrough.

In another embodiment of the present invention, the device has a tubular body.

In another embodiment of the present invention, at least a portion of the catheter is formed of flexible plastic material selected from the group consisting of silicon, polyvinyl chloride, polyurethane, nylon, and polyethylene terphthalate.

In another embodiment of the present invention, the catheter body is formed of stainless steel, nitinol, platinum, or tantalum.

In another embodiment of the present invention, the catheter body is formed of a composite material. Any composite material providing the necessary degree of flexibility and stiffness can be used to make the catheter body.

In another embodiment of the present invention, the diameter of the catheter body at its greatest girth without inflation is between about 1.0 millimeter and about 5.0 centimeters.

In another embodiment of the present invention, the diameter of the device at its greatest girth after inflation of one or more of its inflatable balloons is between about 1.5 mm and about 10 cm.

In another embodiment of the present invention, the device further comprises at least one radio-opaque surface marker, e.g., a radiographic marker or a fluoroscopic marker.

In another embodiment of the present invention, the inflatable balloons of the device are made of materials selected from the group consisting of polyethylene, duralyn, polyethylene terephthalate.

In another embodiment of the present invention, the proximal inflatable balloon of the device is located a distance from the distal end of the catheter, said distance in the range between about 0.5 cm and about 30 cm.

In another embodiment of the present invention, the balloons of the device have a cross-sectional diameter when inflated of between about 1.5 mm and about 10 cm.

In another embodiment of the present invention, the balloons of the device are solvent bonded to the catheter body.

In another embodiment of the present invention, the stent is formed of a plastic deformable material.

The present invention also relates to a method for the precise implantation of an ostial stent at an ostium, comprising the steps of:

(a) inserting a device into a main vessel, said device having a proximal inflatable balloon and a distal inflatable balloon relative to the surgeon or other medical personnel, said distal balloon terminating at a junction with said proximal balloon, said distal balloon having a stent mounted thereon, said stent terminating at or distal to the junction;

(b) advancing the device through the main vessel to a position where the intersection of a main vessel with a branch vessel forms an ostium to be treated or repaired, and, optionally, advancing the device partially through the ostium;

(c) inflating the proximal inflatable balloon;

(d) advancing the device through the ostium until the stent is located entirely within the ostium and the inflated proximal balloon is pressed against the walls of the main vessel;

(e) inflating the distal balloon to thereby expand the stent to contact and be immobilized by the branch vessel;

(f) deflating the proximal and distal balloons simultaneously or in any order; and

(g) withdrawing the device, leaving the stent fixed within the ostium at a position so that the stent covers the stenotic lesions to be treated without protruding into the main vessel.

In one embodiment of the method of the present invention, the catheter is advanced to the ostium by means of a guidewire.

In another embodiment of the present invention, the main vessel is an aorta, and the branch vessel is an artery or vein graft.

Figures 1-4 illustrate one advantage to the device and methods of the present invention. Figure 1 is a cross-section of aorta **1** joining artery **3** showing stenotic lesion **2** at the ostium located at the junction. Prior art methods typically resulted in misplacement of the stent **4**, either at a location too distal of the stenotic lesion (as shown in Figure 2), or at a location too proximal to the stenotic lesion (as shown in Figure 3). For coronary stents, for example, a stent placed too distal to the stenotic lesion results in inadequate treatment of the stenosis. If a stent is placed too proximally at the ostial site, a portion of the stent will protrude into the aorta, providing a potential nidus for formation of thrombus and emboli.

In contrast, the device of the present invention affords appropriate and correct placement of the stent in an ostium. Such appropriate placement is illustrated as one embodiment of the present invention in Figure 4, showing placement of the stent **4** on the stenotic lesions, so that the stent covers the stenotic lesions to be treated without protruding into the main vessel. Also depicted are aorta **1** and artery **3**. A preferred application of the present device is in the repair of stenotic lesions in the coronary arteries. However, it is readily apparent that the device of the present invention is adaptable to the ostia of other bodily structures, including, but not limited to veins, ureters, trachea, and bile ducts.

Figures 5-8 schematically illustrate the method for precise placement of the stent within the ostium to be treated. Figures 9-14 are cutaway views and cross-sections of the catheter in various embodiments.

In Figure 5, the catheter **4** is incompletely inflated, but inserted partially through the ostium with stenotic lesions **2** to be treated. The stent **5** is also shown.

Prior to positioning the stent to cover the stenotic lesions **2** without protruding into the main vessel, the proximal inflatable balloon **6** is inflated so that it provides means to stop further advancement of the catheter **4**, the balloon **6** acting as a stop wall device. Figure 6 illustrates, in one embodiment of the present invention, an inflated proximal balloon **6** with stent **5** needing further advancement for appropriate positioning at the edge **8** of the ostium.

Once the catheter **4** with stent **5** and inflated proximal balloon **6** is inserted or advanced to its furthest extent, the proximal edge **7** of the stent **5** thus substantially coincides with the edge **8** of the ostium. The distal balloon **9** is then inflated to expand the stent **5** for secure placement of the stent **5** at the site of stenotic lesions **2** to be treated. It is readily apparent that the inflated proximal balloon **6** serves as a stop wall device, to give facile placement of the stent **4** at the desired location.

After the stent **4** is placed in the desired location, the balloons in the catheter are deflated, and the catheter is withdrawn, leaving the stent **4** in place. This last step is specifically illustrated by Figure 8, another embodiment of the present invention. The ostial closure due to the stenotic lesions **2** is now removed, so that substantially normal blood flow is restored.

Figures 9-14 illustrate cutaway views and cross-sections of the catheters, and set forth some of the embodiments of the catheters of the present invention.

As schematically shown in the cutaway view of Figure 9, another embodiment of the present invention, a device **4** shows a distal end **10** and a proximal end **11** relative to the surgeon or other medical personnel. The device **4** is generally tubular, and is formed of any one of a variety of materials, including but not limited to plastic, stainless steel or a composite, such as nitinol, platinum, or

tantalum. Suitable plastics include but are not limited to silicon, polyvinyl chloride, polyurethane, nylon, polyethylene terphthalate. The device **4** is sized for insertion into a human blood vessel, and ranges in diameter at its greatest girth without inflation from between about 1.0 millimeters and about 5.0 centimeters. The device **4** is typically tapered at one or both ends (not shown), or at one end and at an intermediate point along the body of device **4** (as in Figures 9,11 and 13).

Secured to the catheter body of device **4** are both a distal inflatable balloon **9** and a proximal inflatable balloon **6**. The proximal inflatable balloon **6** terminates to form a junction **12** with the distal inflatable balloon **9**. The balloons **6** and **9** may be formed of materials known in the art, including but not limited to polyethylene, duralyn and polyethylene terephthalate. The proximal inflatable balloon **6** is located from the distal end **10** a distance in the range between about 0.5 centimeter and about 30 centimeters. The distal inflatable balloon **9** may form the distal end **10**. The device **4** with balloons **6** and **9** have, at their greatest girth, a cross-sectional diameter with inflation of between about 1.5 millimeter and about 10 centimeters. Also depicted in Figure 9 is stent **5**. The balloons **6** and **9** are either formed integrally with the catheter body (as shown in Figure 9) or attached thereto using techniques known in the art (not shown), including solvent bonding. Such integral formation of catheter body and balloon is further depicted in the cross-section of Figure 10, showing the first inflation lumen **14** and a second inflation lumen **15**.

The device **4** contains or is bonded to a first inflation lumen **14** extending therethrough or there along. The first inflation lumen **14** is in fluid communication with the distal inflatable balloon **9** to permit the inflation and deflation thereof. The device **4** also contains or is bonded to a second inflation lumen **15** extending there through or there along, which similarly permits, through fluid communication with the proximal inflatable balloon **6**, the inflation and deflation of the proximal inflatable balloon **6**.

A stent **5** is mountable on the distal inflatable balloon **9**, as also depicted for illustrative purposes in Figures 9, 11, and 13. The stent **5** terminates at or distal to the junction **12** of the distal inflatable balloon **9** and proximal inflatable balloon **6**. The stent **5** is made of materials known in the art, including but not limited to plastic deformable compositions, or biodegradable material, such as polylactic acid or polyglycolic acid. Alternatively, the stent **5** is made of metal, such as stainless steel or a like composite, nitinol, platinum or tantalum.

The stent **5** to be inserted may be covered with any one of a variety of naturally occurring tissues, such as veins, pericardial sections, and the like. Alternatively, stent **5** may be coated with heparin or other substances.

The stent **5** may be configured as a cylinder, or as a cylinder flared at its proximal end (not shown). For placement at some ostial treatment sites, the flaired configuration is preferred for the purpose of treating stenotic lesions at the edge of the ostium or junction of branching vessel and main vessel.

In another embodiment of the present invention, as illustrated in Figure 11, the first inflation lumen **14** is inside of the device **4** and not bonded to the inside wall of device **4**. Also depicted in Figure 11 are stent **5**, proximal inflatable balloon **6** and distal inflatable balloon **9**, and their junction **12**. A cross-section of the device **4** of Figure 11 is shown in Figure 12.

In another alternative embodiment as shown in Figure 13, the device **4** also contains or is bonded to a third lumen **17** extending therethrough or there along. The central lumen receives a guidewire **16** to aid in the advancement of the device through the vessel and in the placement of the device in the ostium to be repaired. A cross-section of the device **4** of Figure 13 is shown in Figure 14.

In the methods of the present invention, there is provided a novel procedure for the precise placement of a stent **5** at the junction of a main vessel (e.g., an aorta **1**), and a branching vessel (e.g., an artery **3**), to repair or treat stenotic lesions **2** at the ostium at such a junction. Such precise placement is illustrated in Figure 4, as one embodiment of the present invention, and shows that an appropriately placed stent should cover the lesions without the protruding into the main vessel.

This method for the implantation of an ostial stent **5** at an ostium comprises the following steps: a first step of inserting a device **4** into a main vessel, said device **4** having a distal inflatable balloon **9** and a proximal inflatable balloon **6** relative to the surgeon or other medical personnel, said proximal balloon **6** terminating at a junction **12** with said distal balloon **9**, said distal balloon **9** having a stent **5** mounted thereon, said stent **5** terminating at or distal to the junction **12**, as illustrated by way of example in Figures 9,11,and 13. Generally, all balloons in the first step are not fully inflated, and may, in some instances, be uninflated.

The second step comprises advancing the device **4** through the main vessel to a position where the intersection of a main vessel with a branch vessel forms an ostium to be treated or repaired. The proximal inflatable balloon **6** is then inflated as a third step, either before or after insertion of the distal end **10** of the device **4** into the ostium of the branching vessel **3.** The stent **5** is placed entirely within the ostium and the inflated proximal balloon **6** is pressed against the walls of the main vessel.

Once the inflated proximal balloon **6** is pressed against the walls of the main vessel, the fourth step of the present method is carried out by inflating the distal balloon **9** to thereby expand the stent **5** to contact and be immobilized by the branch vessel so that both inflatable balloons are inflated.

A fifth step provides withdrawal of the catheter once the stent **5** is in place. The proximal balloon and the distal balloons are deflated, either simultaneously or in any order or sequence. Then the catheter is withdrawn, leaving the stent **5** fixed within the ostium.

In one preferred embodiment of the present invention, the catheter is advanced to the ostium by means of a guidewire.

EXAMPLE

Patient #1

A 55 year old man presents with complaints of exertional chest discomfort. After evaluation by his family physician, he is sent to a cardiologist. The

cardiologist performs a cardiac catheterization and finds a high grade stenosis at the ostium of the right coronary artery. An angioplasty is performed and a stent is placed at the site of the narrowing. Unfortunately, the stent is placed too proximally so that several millimeters of the stent protrude into the aorta. The patient does well and leaves the hospital the next day. Three months later, he again experiences exertional chest discomfort. A cardiac catheterization reveals restenosis or renarrowing of the initial angioplasty site in the right coronary artery. An angioplasty is attempted but the balloon cannot be passed across the lesion probably because the protruding ends of the stent are bent by the catheter used for catheterization. Therefore, the artery is not approachable with angioplasty techniques and the patient has to undergo bypass surgery.

Patient #2

A 63 year old woman has undergone coronary artery bypass grafting in 1990. She does well until one month prior to admission when she begins experiencing exertional chest pain. A catheterization shows a high grade narrowing at the ostium of the vein graft to the obtuse marginal vessel. Angioplasty is attempted and a stent is placed. Unfortunately, the stent is placed distal to the lesion and the inaccurate placement of the stent is not noticed because the angioplasty balloon used after stent placement pressed the plaque against the graft wall. Twenty hours after her procedure, the patient develops severe chest discomfort. An electrocardiogram is consistent with an acute myocardial infarction. She is rushed back to the cath lab and is found to have a complete occlusion of her vein graft at its ostium. A repeat angioplasty is performed. The patient expires during the procedure.

Patient #3

A 48-year-old man presents to his physician with complaints of chest pressure with exertion. Cardiac catheterization reveals a high grade narrowing at the ostium of the RCA. Using the current invention, a stent is placed appropriately

at the ostium of the RCA. The procedure is completely uncomplicated and the patient is discharged the next day. He remains completely free from symptoms.

While the foregoing specification teaches the principles of the present invention, with examples provided for the purpose of illustration, it will be understood that the practice of the invention encompasses all of the usual variations, adaptations, and modifications, as come within the scope of the following claims and its equivalents.

What is claimed is:

1. A device for implanting an ostial stent comprising

(a) a catheter, said catheter having a proximal end and a distal end relative to the surgeon or other medical personnel;

(b) a distal inflatable balloon for setting a stent;

(c) a first inflation lumen, extending through or outside of the catheter to permit inflation and deflation of the distal inflatable balloon;

(d) a proximal inflatable balloon as a stop wall device, said proximal inflatable balloon forming a junction with said distal balloon; and

(e) a second inflation lumen, extending through or outside of the catheter to permit inflation and deflation of the proximal inflatable balloon.

2. The device of claim 1, further comprising a stent, said stent mountable on the distal inflatable balloon, said stent terminating at or distal to the junction of the proximal inflatable balloon and the distal inflatable balloon.

3. The device of claim 1, further comprising a central lumen extending through the catheter, the central lumen receiving a guidewire therethrough.

4. The device of claim 1, wherein the catheter has a tubular body.

5. The device of claim 1, wherein at least a portion of the catheter is formed of flexible plastic material selected from the group consisting of silicon, polyvinyl chloride, polyurethane, nylon, and polyethylene terephthalate.

6. The device of claim 1, wherein the catheter body is formed of stainless steel, nitinol, platinum, or tantalum.

7. The device of claim 1, wherein the catheter body is formed of a composite material.

8. The device of claim 1, wherein the diameter of the device at its greatest girth without inflation is between about 1.0 mm and about 5.0 cm.

9. The device of claim 1, wherein the diameter of the device at its greatest girth after inflation of one or more of its inflatable balloons is between about 1.5 mm and about 10 cm.

10. The device of claim 1, further comprising at least one radio-opaque surface marker.

11. The device of claim 10, wherein the marker is radiographic.

12. The device of claim 10, wherein the marker is fluoroscopic.

13. The device of claim 1, wherein the inflatable balloons are made of materials selected from the group consisting of polyethylene, duralyn, and polyethylene terephthalate.

14. The device of claim 1, wherein the proximal balloon is located a distance from the distal end of the catheter, said distance in the range between about 0.5 cm and about 30 cm.

15. The device of claim 1, wherein the balloons have a cross-sectional diameter when inflated of between about 1.5 mm and about 10 cm.

16. The device of claim 1, wherein the balloons are solvent bonded to the catheter body.

17. The device of claim 1, wherein the ostial stent is formed of a plastic deformable material.

18. A method for the precise implantation of an ostial stent, comprising the steps of:

(a) inserting a device into a main vessel, said device having a proximal inflatable balloon and a distal inflatable balloon relative to the surgeon or other medical personnel, said distal balloon terminating at a junction with said proximal balloon, said distal balloon having a stent mounted thereon, said stent terminating at or distal to the junction;

(b) advancing the device through the main vessel to a position where the intersection of a main vessel with a branch vessel forms an ostium to be treated or repaired, and, optionally, advancing the device partially through the ostium;

(c) inflating the proximal inflatable balloon;

(d) advancing the device through the ostium until the stent is located entirely within the ostium and the inflated proximal balloon is pressed against the walls of the main vessel;

(e) inflating the distal balloon to thereby expand the stent to contact and be immobilized by the branch vessel;

(f) deflating the proximal and distal balloons simultaneously or in any order; and

(g) withdrawing the device, leaving the stent fixed within the ostium at a position so that it covers the stenotic lesions to be treated without protruding into the main vessel.

20. The method of claim 19, wherein the device is advanced to the ostium by means of a guidewire.

21. The method of claim 19, wherein the main vessel is an aorta, and the branch vessel is an artery or vein graft.

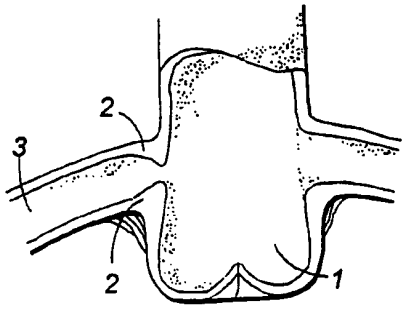

FIG. 1

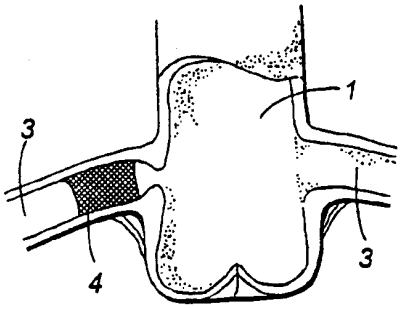

FIG. 2

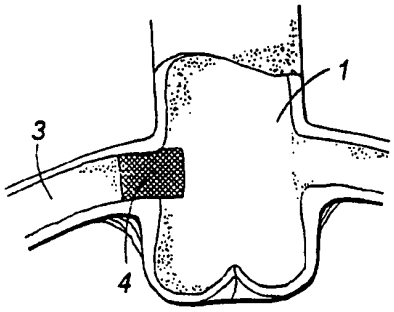

FIG. 3

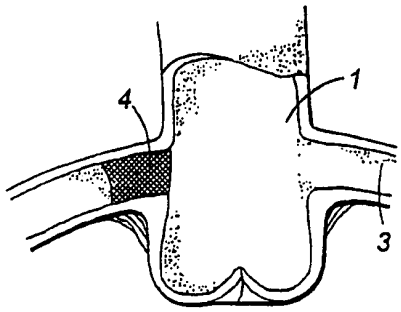

FIG. 4

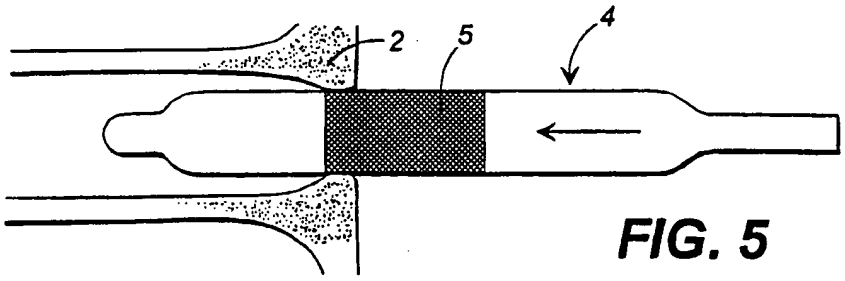

FIG. 5

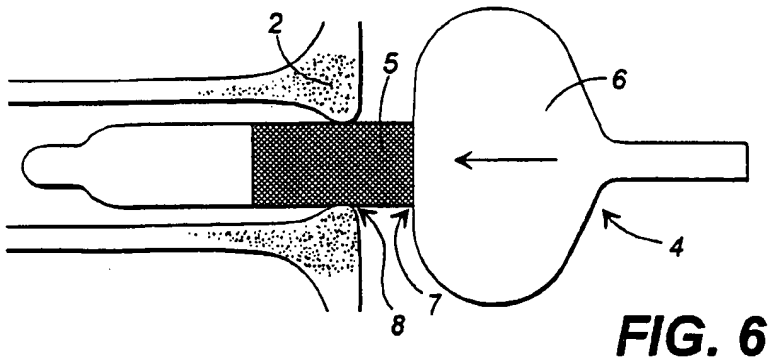

FIG. 6

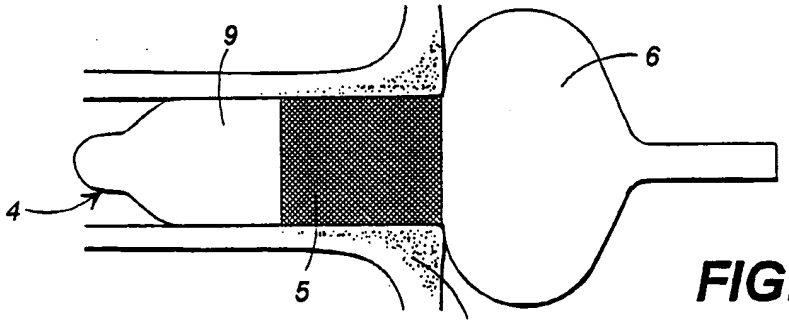

FIG. 7

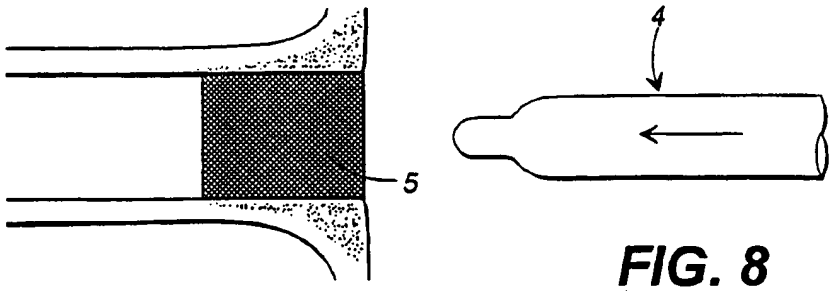

FIG. 8

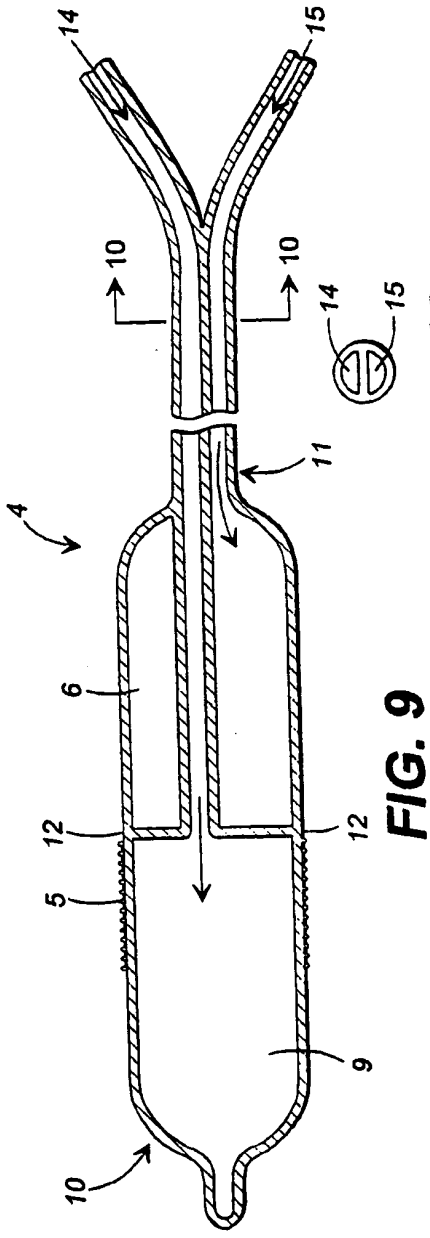

FIG. 9

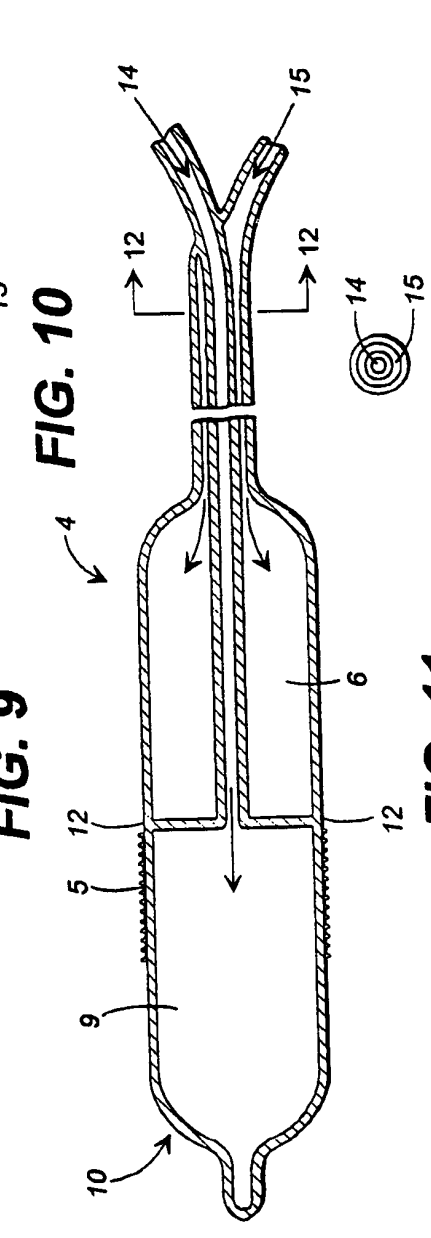

FIG. 11

FIG. 10

FIG. 12

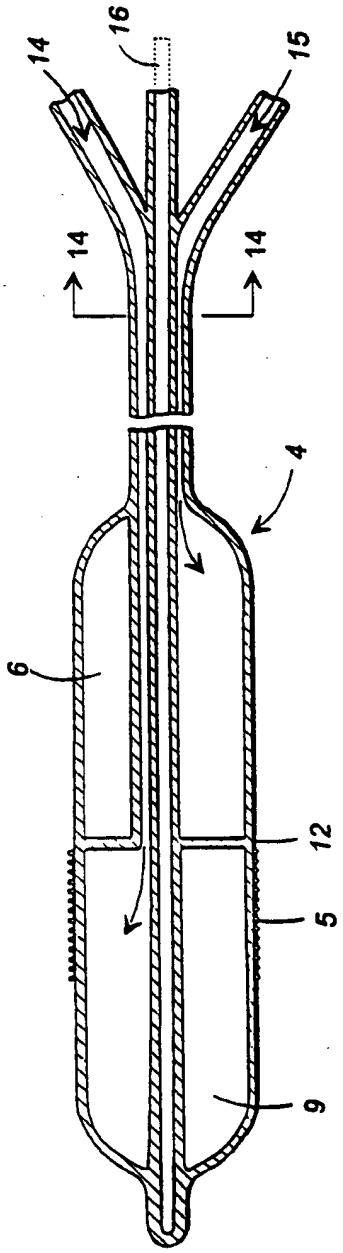

FIG. 13

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/00754

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 11/00
US CL :604/96, 102; 606/108, 194, 198

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96, 102; 606/108, 194, 198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US 5,817,057 A (BERENSTEIN et al) 06 October 1998, entire document.	1-21
X,P	US 5,749,890 A (SHAKNOVICH) 12 May 1998, Figs. 1-15.	1-21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

23 MARCH 1999

Date of mailing of the international search report

14 APR 1999

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